

II. A Response to the Office Action:

A. Status of the Claims

Claims 33-36 and 38-58 were pending at the time the Action was issued from the U.S. Patent Office. Claims 33-36, 38-39, 41-42, 44-48, 50, 52, and 54-57 have been amended, claims 40, 43, and 53 have been canceled, and claims 59-60 have been added. Support for the amendments and new claims can be found throughout the specification and claims as originally filed. Claims 33-36, 38-39, 41-42, and 44-60 therefore are currently pending.

B. Telephone Interview With the Examiner

Applicants representative, Michael R. Krawzsenek, and Examiner Jeanine A. Goldberg conducted a telephone interview on December 16, 2004. The present invention, current rejections, and potential amendments to the claims were discussed during the telephone call. No agreement was reached.

C. The Indefiniteness Rejections Are Overcome

The Action rejects claims 33-43 and 47 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Two separate indefiniteness rejections exist.

Applicants disagree with these rejections. The present claims are definite and satisfy all of the requirements under 35 U.S.C. § 112, second paragraph. Applicants address each rejection separately.

1. Claims 34-35 Are Definite

The Action takes the position that claims 34-35¹ are indefinite because the phrase “suitable for digestion together with said biological sample” is subject to multiple interpretations. Applicants note that this phrase has been deleted. The present indefiniteness rejection is therefore rendered moot, and the rejection of claims 33-34 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

2. Claims 36-43 and 47 Are Definite

Claims 36-43 and 47 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness over the use of the phrase “substantially irreversibly adhered together.” The Action contends that this phrase is “relative” which renders the claim indefinite. It appears that the Action is concerned with the term “substantially.”

Applicants traverse. The phrase “substantially irreversibly adhered together” is definite and satisfies all of the requirements of 35 U.S.C. § 112, second paragraph. A person of skill in the art would understand the scope of this claim when read in light of the specification. This is confirmed by the MPEP which notes that the term “substantially” is an acceptable claiming term. *See* MPEP § 2173.05(b)(D) (listing cases holding that the use of the term “substantially” in a claim does not make that claim indefinite).

In an effort to further the prosecution in this case and to obtain commercially relevant claims at this time, Applicants have removed term “substantially” from the claims. This rejection should therefore be withdrawn. It is Applicants’ position that the claims that no longer recite the term “substantially” are now broader in scope.

¹ Applicants note that claims 33-34 include the disputed language. Claim 35 does not include this language. For the purposes of this response, Applicants will address claims 33 and 34, and not claim 35.

E. The Anticipation Rejections Are Overcome

1. Claims 33-35, 40-41, 43, 45-46, and 48-58 Are Not Anticipated by U.S. Patent No. 5,858,770 to Perlman

Claims 33-35, 40-41, 43, 45-46, and 48-58 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,858,770 to Perlman. The Action contends that Perlman teaches a cell culture plate with an oxygen and carbon-dioxide permeable waterproof sealing membrane. It is also contended by the Action that “[t]he microwell plate is suitable for allowing digestion of a biological sample with the plate.” The Action, page 6. *Id.*

Applicants traverse this rejection. Perlman does not anticipate the present claims, either expressly or inherently.

Applicants’ independent claim 33, for example, recites “a base sheet arranged so that the biological sample is positioned thereon, wherein a portion of the base sheet partially dissolves in a solution.” Independent claim 55, for example, recites “a base sheet arranged so that the biological sample may be positioned thereon, the base sheet comprising an absorbent material that is secured to a portion of a front surface of the base sheet.” At least these elements do not appear to be disclosed or suggested by Perlman.

Rather, Perlman appears to disclose a cell culture plate that can be used for culturing and manipulating living cells. *See* Perlman, col. 1, lines 6-11. The cell culture plates can be sealed with an oxygen and carbon dioxide-permeable waterproof sealing membrane. *Id.* The membrane allows living cells “to grow and survive within a sealed leak-proof culture plate.” *Id.* at col. 2, lines 5-6.

Because Perlman does not teach or suggest every element of the present invention, the anticipation rejection cannot be maintained. The rejection of claims 33-35, 40-41, 43, 45-46, and 48-58 should therefore be withdrawn.

2. Claims 33-36, 38-39, and 41-47 Are Not Anticipated By U.S. Patent No. 3,733,025 to Hiersteiner

The Action rejects claims 33-36, 38-39, and 41-52 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,733,025 to Hiersteiner. The Action contends that this reference discloses an envelope which has a tamper-evident storage means for storing a sample. The Action also states that the envelope has a backing sheet which is releasably secured to the surface of the cover sheet facing the base sheet.

Applicants traverse. Hiersteiner does not anticipate claims 33-39 and 41-47, either expressly or inherently.

Hiersteiner does not appear to disclose “a base sheet arranged so that the biological sample is positioned thereon, wherein a portion of the base sheet partially dissolves in a solution; a polymeric sheet secured to the base sheet; and a backing sheet releasably secured to the polymeric sheet, wherein the storage structure allows at least partial digestion of the biological sample.”

Rather, this reference appears to disclose a standard office envelope. The envelope appears to include a seal flap that:

... has a portion reinforced by folding an adhesive connection, the reinforced portion being divided from the remainder of the seal flap by a line of tear perforations. A releasable adhesive connection is made between the outside of said portion and the back of the envelope whereby said portion may be peeled across the back of the envelope to open the same.

See Hiersteiner, Abstract. There does not appear to be any disclosure of, for example, “a polymeric sheet secured to the base sheet.” The anticipation rejection therefore cannot be maintained.

Applicants request that the rejection of claims 33-39 and 41-47 as being anticipated by Hiersteiner be withdrawn.

3. Claims 33-35, 41, and 43-47 Are Not Anticipated By U.S. Patent No. 3,965,888 to Bender

The Action rejects claims 33-35, 41, and 43-47 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,965,888 to Bender. The Action contends that this reference discloses a specimen collector and holder. It further contends that the holder includes a transparent foldable segment that is used to collect the specimen and retain the back-folded segment for visual examination.

Applicants traverse. Bender does not anticipate claims 33-35, 41, and 43-47, either expressly or inherently.

Bender appears to disclose “[a] specimen holder ... for collecting and examining a specimen collected from a body.” Bender, Abstract. This reference does not appear to disclose Applicants’ claimed element of “a base sheet arranged so that the biological sample is positioned thereon, wherein a portion of the base sheet partially dissolves in a solution.”

Because the cited reference does not appear to teach or suggest every element of the present invention, the anticipation rejection cannot be maintained. The rejection of claims 33-35, 41, and 43-47 should therefore be withdrawn.

4. Claims 33-36, 38-39, and 42-52 Are Not Anticipated By U.S. Patent No. 6,007,104 to Draper

The Action rejects claims 33-36, 38-39, and 42-52 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,007,104 to Draper. The Action contends that this reference discloses a multilayer medical device and form for collecting samples and retaining information. The Action states that the left side of the device can take samples and the right side includes insurance and individual information. According to the Action, the device contains a base sheet and a cover sheet with an adhesive.

Applicants traverse. Draper does not anticipate claims 33-36, 38-39, and 42-52, either expressly or inherently.

Draper appears to disclose “[a] combined medical device and form (20) having a unitary substrate (22) which is divided into a medical device portion (24) and a form portion (26). The form portion (24) of the substrate includes an informational section (30, 32, 34), and form identification material (36).” Draper, Abstract. This reference, however, does not appear to disclose the claimed element of “a base sheet arranged so that the biological sample is positioned thereon, wherein a portion of the base sheet partially dissolves in a solution.”

Because the cited reference does not appear to teach or suggest every element of the present invention, the anticipation rejection cannot be maintained. The rejection of claims 33-36, 38-39, and 42-52 should therefore be withdrawn.

G. Conclusion

Applicants believe that the present document is a full and complete response to the Office Action dated August 20, 2004. Applicants submit that the present case is in condition for allowance and such favorable action is requested.

III. A Petition for a Three Month Extension of Time:

Pursuant to 37 C.F.R. § 1.136(a), Applicants petition for an extension of time of three months to and including February 20, 2005, in which to respond to the Office Action dated August 20, 2004. Pursuant to 37 C.F.R. § 1.17, a check in the amount of \$510.00 is enclosed, which is the process fee for a three-month extension of time for a small entity status. If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included, the Commissioner is authorized to deduct or credit the appropriate fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/GENS:008US.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3020 with any questions, comments or suggestions relating to this patent application.

Respectfully submitted,



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